

9/94/997

PATENT
1112-1-052CON

REMARKS

Claims 1-15 are pending in the application. Claims 4-8 and 10-15 are withdrawn by the Examiner, and Applicant cancels Claim 2 without prejudice and adds new independent Claim 16. After entry of the present Amendment, claims 1 and 3-16 will be pending. Claims 1, 3 and 9 are rewritten, and Claim 9 is now presented in independent form.

Objections to the Drawings

The Examiner indicates that the drawings are objected to for reasons set forth in PTOL-948. However, Applicants note that Form PTOL-948 is not among the papers received in the Office Action mailing. Further, Applicant's representative was unsuccessful at contacting the Examiner prior to the response due date, and respectfully requests that the Examiner fax the form to the undersigned at (201) 343-1684, and the matter will be handled promptly.

Claim of Priority

To properly claim priority, Applicant inserts as the first sentence of the application the proper cross-reference information.

Specification

The paragraphs of the specification containing the portions indicated by the Examiner as needing correction have been corrected. First, the trademark TENTAGEL and other diagnostics and reagents are capitalized and given the generic terminology. Second, Applicants insert the appropriate patent number in place of references to applications in instances of incorporation by reference as the Examiner requests.

Rejection Under 35 U.S.C. §112

Regarding written description

Claims 1-3 and 9 are rejected under 35 U.S.C. 112, first paragraph, for reason of written description. Applicants herein amend the claims removing the word “corresponding” that is believed responsible for the confusion as to what the claims encompass. In its place, Applicants insert “consisting essentially of.” With these amendments, the precise structure of the family of claimed troponin I fragments is clear to the skilled artisan. Applicants further remove the language “represented by” from claim 3 thereby clarifying that SEQ ID NO:2 is intended.

The Examiner adds that there is no reference to a sequence of troponin I so that the reference to amino acids 20 to 30 to about 95 to about 115 is unclear in claims 1 and 9. Applicants herein clarify the language by specifying that the amino acids refer to the sequence of human cardiac troponin I, and that the amino acids 20 to 30 refer to the N-terminus and 95 to 115 refer to the C-terminus of the peptide. Claim 9 is rewritten in independent form adding clarity to the description of the claimed fragments as noted.

With regard to the Examiner’s mention of the failure of the claims to recite any function of the encompassed polypeptides, Applicant contends that with the amended claim language, the intended fragments are adequately defined and the inclusion of a functional limitation is thus unnecessary. The Examining Guidelines are clear that a mixture of structural and functional language may be used to fulfill the written description requirement. Notwithstanding, Applicants contend that the specification is an adequate and acceptable source for various functions of the claimed polypeptides.

Furthermore, Applicant also includes a new, independent claim to the isolated peptide depicted in SEQ ID NO:2.

No issue of new matter arises by way of these changes, since express support may be found in the specification at page 4, second full paragraph, lines 11-22. Applicants merely employ the language provided therein in conjunction with ordinary claim language vehicles such as "consisting essentially of." Moreover, Applicants remove the unusual recitation "represented by" so that the claim language is in closer conformity to the express disclosure "depicted in SEQ ID NO:2."

In light of the foregoing and the claim amendments, Applicant believes that the written description rejection has been overcome and withdrawal of the rejection is requested.

Regarding enablement

Claims 1-3 and 9 (these claims are believed to be those under rejection in Paragraph 8) are rejected under 35 U.S.C. 112, first paragraph, with regard to enablement. The Examiner's concern is believed to center around the word "corresponding" in Claim 1.

Applicant respectfully traverses the rejection. In light of the amendments to the claims to replace the word "corresponding" and provide better language, and the corresponding arguments presented above, withdrawal of the rejection is requested.

Rejection under 35 U.S.C. 112, second paragraph

Claims 1-3 and 9 are rejected under 35 U.S.C. 112, second paragraph, for indefiniteness. The rejection is based upon the word "corresponding" and the failure of the claims to recite a particular sequence upon which they are based. This rejection is also believed overcome by the amendments contained herein. The offending language is removed, and as is provided in the specification at page 4, second full paragraph, Applicants clarify that the reference sequence is that of human cardiac troponin I.

Rejection Under 35 U.S.C. §102

Morjana *et al.*

Claims 1-2 and 9 are rejected under 35 U.S.C. §102(b) as being anticipated by Morjana *et al.* (WO97/19955). The Examiner asserts that Morjana *et al.* teach human cardiac troponin I fragments generated from human recombinant troponin I by chemical cleavage, principally a 153-amino acid fragment, for which longer or shorter forms by a few amino acids are described. The Examiner indicates that Morjana's isolated polypeptide corresponds with Applicant's.

Applicant respectfully traverses the rejection. By the foregoing amendment to the claims to eliminate the use of the words "corresponding" and "comprising" in order to clearly point out that Applicant's fragments in Claim 1 are around 95-115 amino acids in length, and in Claim 9 are around 65 to 95 amino acids in length, Applicant contends the claimed fragments are not anticipated by or suggested by Morjana's. Withdrawal of the rejection is requested.

Moses *et al.*

Claims 1-2 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Moses *et al.* (WO 97/30085). The Examiner asserts that the Moses *et al.* teach fragments of human cardiac troponin I of various lengths, at least 50, 75, 100 or 120 amino acids.

Applicant traverses the rejection. Moses *et al.* is concerned with therapeutic activities associated principally with a different form of troponin I, namely the fast-twitch (*i.e.*, skeletal) troponin I, and cardiac troponin I is mentioned only in passing with no teaching or description of any specific fragments of human cardiac troponin I (or even from wherein the molecule to obtain such fragments). Moreover, Moses *et al.* teach that the full-length form of fast-twitch (skeletal, *not* cardiac) troponin I inhibits angiogenesis, and only postulates that fragments of skeletal, not cardiac, may also be similarly useful, Moses *et al.* do not teach or suggest any fragments of human cardiac troponin I, nor do they teach or suggest from which part of the molecule to obtain

such fragments. At best, Moses *et al.* provide more than an abstract criminal, though, even though it is possible, there is no showing of suggestion or motivation to combine the elements of such fragments. Applicant alleges that the fragments of cardiac troponin I that are as identified among various uses in the prior art, and in combination with amended claim language, are used earlier, withdrawal of the rejection is requested.

Potter *et al.*

Claims 1, 3 and 9 are rejected under 35 U.S.C. §102(e) as being anticipated by Potter *et al.* (WO 97/39102). The Examiner asserts that Potter *et al.* teach recombinant human cardiac troponin I that corresponds to Applicant's SEQ ID NO:2.

Applicant respectfully traverses the rejection. As noted above, Applicant amends the claims by eliminating the words "corresponding" and "comprising" such that Applicant's human cardiac troponin I fragments do not read on the Potter *et al.* troponin I. In light of the foregoing, withdrawal of the rejection is courteously requested.


Fees

No fees are believed to be necessitated by the instant response. However, should this be in error, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or to credit any overpayments.

CONCLUSION

Entry of the foregoing reply into the record is respectfully requested. An early allowance is earnestly sought.

Respectfully submitted,


J. David Smith, Esq.
Attorney for Applicant(s)
Registration No. 39,839

KLAUBER & JACKSON
411 Hackensack Avenue
Hackensack NJ 07601
Tel: (201) 487-5800